

Amend Ph 302.02, effective 3-26-05 (Doc. #8316) by amending paragraph (a), and adding new paragraph b and renumbering current paragraph (b) as (c), to read as follows:

(a) The preliminary application for reciprocal licensure may be obtained from the office of the board or from the National Association of Boards of Pharmacy, 1600 Feehanville Drive, Mount Prospect, Illinois, 60056, (847) 391-4406. This application shall be filed with the National Association of Boards of Pharmacy.

(b) The applicant shall include the following on the application:

- (1) Name, address and telephone number of the applicant;
- (2) Date and place of birth of the applicant;
- (3) Record of convictions of violations of federal, state or local liquor or drug-related laws;
- (4) Any disciplinary actions taken by any other state or pharmacist licensing jurisdiction against the applicant;
- (5) Any felony convictions;
- (6) Pharmacy college attended, graduation date and degree awarded;
- (7) State of original licensure as a pharmacist, license number and date of original issuance; and
- (8) Practice as a pharmacist and employment after original licensure.

(c) The candidate shall file a completed application NABP Form P provided by the National Association of Boards of Pharmacy

Amend Ph 302.07(b), effective 2-5-96, (Doc. #6181-B), as amended effective 2-1-99 (Doc. #6933), to read as follows:

(b) The candidate shall pay the prescribed fee of \$185.

Amend Ph 302.08(c), effective 2-5-96, (Doc. #6181-B), as amended effective 2-1-99 (Doc. #6933), to read as follows:

(c) Any candidate for re-examination of the jurisprudence examination shall remit the prescribed fee of \$185 prior to being re-examined.

Amend Ph 303.02 (d), (h), and (j), effective 3-26-05, (Doc. #8316), to read as follows:

(d) A licensed pharmacist shall be on duty at all times when the prescription department is open to the public and during any absences by the pharmacist, the prescription department shall be secured except as is provided in Ph 704.01(b).

(h) No prescription, new or refill, shall be left with or accepted by clerks, pharmacy technicians as defined in RSA 318:1, XI-a or pharmacy interns as provided in RSA 318:42, IX when the prescription department is closed except as is provided in Ph 704.01(b).

(j) No telephone prescriptions, new or refill, shall be accepted by clerks, pharmacy technicians or pharmacy interns when the prescription department is closed except as is provided in Ph 704.01(b).

Amend 306.01(d), effective 3-26-05, (Doc. #8316), to read as follows:

(d) In a publicly traded, multi-tiered corporation, the lowest tier of the corporate structure doing business as a pharmacy in the State of New Hampshire.

Readopt with amendment Ph 308.05, effective 3-26-05, (Doc. #8316), to read as follows:

Ph 308.05 Other Licensing Fees. The annual licensing fee for federally funded clinics under the direction of the department of health and human services shall be \$150 and for drug abuse treatment centers shall be \$150.

Adopt Chapter Ph 600 to read as follows:

CHAPTER Ph 600 LIMITED RETAIL DRUG DISTRIBUTOR

Statutory Authority: RSA 318:51-b

PART Ph 601 LICENSING OF LIMITED RETAIL DRUG DISTRIBUTORS

Ph 601.01 License required

(a) No person shall act as a limited retail drug distributor, as defined in RSA 318:1,VII-a, without first obtaining a license to do so from the board according to RSA 318:51-b.

(b) No license shall be issued or renewed for a limited retail drug distributor unless the same shall be operated in a manner prescribed by RSA 318:51-b and according to Ph 600.

(c) Separate licenses shall be required for each site owned and operated by the limited retail drug distributor.

(d) The board shall provide, on an annual basis, a license renewal to all licensed limited retail drug distributors.

(e) The prescribed fee for annual and renewal licenses for limited retail drug distributors shall be:

- (1) For clinics under contract with the department of health and human services (DHHS), \$150; and
- (2) For methadone maintenance/detoxification treatment centers, \$150.

Ph 601.02 Obtaining and Filing a License Application

Applications for licensure of limited retail drug distributors may be obtained from and filed at the board office, identified in Ph 103.03.

Ph 601.03 Application Contents.

(a) The applicant for licensure shall supply, on form MM-1, at least the following:

- (1) Name of the facility;
- (2) Address of the actual location where business is conducted;
- (3) Identification of ownership;
- (4) Hours of operation;
- (5) List of persons with access to the drug supply;
- (6) Signature of the person responsible for the licensed location and date signed;
- (7) Identity of the consultant pharmacist; and
- (8) Identity of the medical director.

(b) The applicant shall also submit a scaled drawing of the facility.

(c) The applicant shall supplement the application specified in (a) and (b) above with any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements of part Ph 600.

(d) If the applicant is a corporation, or the limited retail drug distributor will be operated under a corporate name, a certificate from the NH secretary of state attesting to the documents creating the corporate person and any amendment(s) thereof to the certificate of incorporation, or authorizing it to do business in the state of New Hampshire under the corporate name.

(e) If the applicant proposes to hold, store or dispense controlled substances as a methadone maintenance/detoxification facility, the application shall be supplemented with the following information:

- (1) A brief description of the security system; and
- (2) A list of all persons with access to the controlled substances.

(f) The applicant shall supplement the application specified in (e) above with any certificates, affidavits, plans, documents or other information sufficient to show full compliance with all of the requirements for operation of a drug abuse treatment facility.

(g) If the application is for a methadone maintenance/detoxification facility, the applicant shall submit the current registration number issued by the federal drug enforcement administration (DEA).

Ph 601.04 Consultant Pharmacist. All applicants licensed under the provisions of RSA 318:51-b shall have a written contract with a pharmacist, licensed in NH, to serve as a consultant on all matters relating to procurement, storage and dispensing of prescription drugs as defined in RSA 318:1, XVII.

Ph 601.05 Changes in Supporting Information. The applicant shall notify the board, immediately, of any changes of information from that which was submitted on the original application pursuant to Ph 601.03.

Ph 601.06 Renewal Applications.

(a) The license period shall be from July 1 thru June 30 of the following year.

(b) Applications for renewal of a license to operate as a limited retail drug distributor shall consist of the application as described in Ph 601.03 and the prescribed fee as indicated in Ph 601.01(e).

Ph 601.07 Temperature. The temperature in any area wherein drugs are stored, manufactured, compounded or dispensed, shall, at all times, be in compliance with the standards established by the United States Pharmacopoeia as defined in Ph 701.02(r).

Ph 601.08 Quarantine. Any drug, which is adulterated as defined in Ph 701.02(a) or misbranded as defined in Ph 701.02(i), shall be removed from the routine stock and held in a specifically designated secure area of the facility pending proper and safe disposition.

Ph 601.09 Space. Drugs shall be housed in a well-lighted and ventilated room or department with clean and sanitary surroundings.

Ph 601.10 Security.

(a) That portion of the facility where drugs are stored, compounded or dispensed, shall be lockable so as to prevent entry into that area by any person or persons without the knowledge of the authorized individuals on duty, or when the facility is not open.

(b) If the facility contains controlled substances, it shall be equipped with a suitable alarm system as referenced in Ph 309.06.

(c) Methadone maintenance/detoxification facilities shall ensure that all access from outside their premises is secure. This shall include, but not be limited to, the installation of adequate lighting to illuminate the outside perimeter of the premises.

(d) All controlled substances shall be stored pursuant to the security provisions outlined in 21 CFR 1301.72(a).

(e) For those facilities which are open to the public 24 or more hours per week, the consultant pharmacist shall visit, at least monthly, all areas of the facility where drugs are stored to ensure that they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any drugs not conforming to these standards shall be removed from stock. For facilities which are open to the public less than 24 hours per week, such visits shall be conducted on a quarterly basis.

(f) The consultant pharmacist shall create a written record of each monthly and/or quarterly inspection, specified in (e), which shall be maintained on site and available to the board upon request.

(g) The pharmacist shall ensure that the areas specified in (e) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(h) The consultant pharmacist shall develop a distribution system, which shall prevent the illegal diversion of drugs. Where applicable, the inventory of all schedule II controlled substances and other controlled drugs as required by federal law stored in any area of the facility, shall be checked by 2 persons at least every 24 hours and accountability records shall be completed by the nursing or medical staff and maintained on-site for inspection by the consultant pharmacist.

Ph 601.11 Dispensing Practices.

(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, physician, advanced registered nurse practitioner, physician assistant, or registered nurse, as identified in RSA 318:42, VII (a), in compliance with state and federal pharmacy-related laws and rules.

(b) No finished prescription shall be left outside of the drug storage area of the facility for pick-up when the licensed practitioner is not present at the facility.

(c) In the case of methadone maintenance/detoxification facilities, all drugs shall remain in the designated and secured medication room at all times.

Ph 601.12 Deliveries.

(a) All drug order deliveries containing prescription drugs shall be delivered only when a licensed practitioner is on the premises in order to secure such drug orders.

(b) In the case of methadone maintenance/detoxification facilities, drug deliveries may be accepted only by the licensed practitioner or other individuals identified according to the requirements of 21 CFR 1301.74(h).

Ph 601.13 Access to Drug Supply. Only the pharmacist, physician, advanced registered nurse practitioner, physician assistant or registered nurse, as identified in RSA 318:42, VII (a), shall have access to the drug supply.

Ph 601.14 Dispensing Records

(a) A readily retrievable record, completed by the nursing or medical staff, shall be made of all administration or dispensing of prescription drugs from the facility.

(b) The record, as specified in (a) above, shall be separate from the patient's medical record and include:

- (1) Name and address of the patient;
- (2) Date of administration or dispensing;
- (3) Name, strength and quantity of drug(s) administered or dispensed;
- (4) Identity of the prescriber; and
- (5) Signature of the person administering or dispensing.

(c) Methadone maintenance/detoxification facilities shall maintain a dispensing log, completed by the nursing or medical staff, containing the following information:

- (1) Name of substance;
- (2) Strength of substance;
- (3) Dosage form;
- (4) Date administered;
- (5) Patient name;
- (6) Amount consumed;
- (7) Amount and dosage form taken home; and
- (8) Dispenser's signature.

(d) Records of administrations and dispensing as specified in (b) and (c) above shall be maintained for a period of 4 years. Such records shall be open to inspection by the pharmacy board and its agents.

Ph 601.15 Prescription Labels.

(a) Whenever an authorized practitioner dispenses a controlled drug, as defined in RSA 318-B:1-a and b, or a non-controlled prescription drug, as defined in RSA 318:1, XVII, he/she shall affix to the container in which such drug is dispensed, a label showing at least:

- (1) Name and address of the facility;
- (2) Name of the patient;
- (3) Date dispensed;
- (4) Name, strength and quantity of drug dispense;
- (5) Directions for use;
- (6) Name of the prescribing practitioner;
- (7) Name or initials of the dispensing practitioner; and
- (8) All pertinent auxiliary labels.

Ph 601.16 Labeling Exemption. The labeling requirements, as specified in Ph 601.15, shall be exempted when medication is being administered, for immediate consumption, such as in a methadone maintenance/detoxification facility.

Ph 601.17 Violations. Any person who distributes legend drugs according to RSA 318:51(b) and the provisions of Ph 600, shall be subject to disciplinary action as provided in RSA 318:29.

Amend 701.02(a), effective 2-5-96 (Doc. #6181-B), as amended effective 2-1-99 (Doc. #6933), as amended effective 8-1-01 (Doc. #7535), (3-26-05, (Doc. #8316), to read as follows:

(a) "Adulterated drug" means any drug:

- (1) That is contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to man or other animals;
- (2) Which has been manufactured, composed, prepared, stored, or dispensed in such a manner which may cause it to be contaminated, decomposed, deteriorated, sub-potent, super-potent, or otherwise unsafe for administration to man or other animals; and
- (3) Which can be defined as an adulterated drug under the provisions of RSA 146:4 or 21 U.S.C. 351 of the Food, Drug, and Cosmetic Act.

Amend 701.02(c), effective 2-5-96, (Doc. #6181-B), as amended effective 2-1-99 (Doc. #6933), to read as follows:

(c) "Distributor" means a person or persons who supplies or facilitates the supply of prescription drugs to someone other than the patient, including, but not limited to, manufacturers, repackers, brokers and wholesale drug distributors.

Amend 701.02(n), effective 2-5-96, (Doc. #6181-B), as amended effective 2-1-99 (Doc. #6933), to read as follows:

(n) "Signature" means:

- (1) The handwritten name of an individual affixed by the hand of that individual to a document;
- (2) An electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign a document or record; or
- (3) An electronic signature.

Amend 702.01(b)(3), effective 3-26-05, (Doc. #8316), to read as follows:

- (3) Refrigeration storage equipment used exclusively for drugs.

Amend 702.05(a), effective 3-26-05, (Doc. #8316), to read as follows:

(a) Except as provided in Ph 704.01(b), no pharmacy shall be open unless a pharmacist is on duty in the pharmacy. At all times during which a pharmacist is not on duty in the pharmacy, all entry to the pharmacy shall be barred by locked doors.

Amend 703.02(b)(2), effective 3-26-05, (Doc. #8316), to read as follows:

(2) The identity of the manufacturer or source of the bulk chemicals, the lot number and the expiration date of each ingredient contained in the formula;

Readopt with amendments Ph 704.01, effective 2-5-96, (Doc. #6181-B), as amended effective 2-1-99 (Doc. #6933), to read as follows:

Ph 704.01 Presence of Pharmacists.

(a) Prescription drugs and devices shall be dispensed only in the presence of and under the immediate supervision of a pharmacist except as provided in (b).

(b) Whenever the pharmacy is staffed by a single pharmacist, the pharmacist may take a lunch/rest break for a period of up to 30 minutes without closing the pharmacy and removing pharmacy technicians and pharmacy interns from the pharmacy if the pharmacist reasonably believes that the security of the prescription drugs will be maintained in his or her absence and in accordance with the following:

- (1) Lunch breaks shall be scheduled as close as possible to the same time each day in order for the patients to become familiar with the approximate times of lunch breaks;
- (2) Lunch breaks shall be part of the total hours worked each week;
- (3) The pharmacist shall remain on the store premises during the lunch break and be available for emergencies. Emergencies shall be defined by the patient;
- (4) If 2 or more pharmacists are on duty, the pharmacists shall stagger their lunch breaks so that the pharmacy is not left without a pharmacist on duty;
- (5) Whenever the pharmacist temporarily leaves the prescription department for a lunch break, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed in full view of patients approaching the prescription department service area. The signage shall also indicate the time when the pharmacist is to return;

- (6) Only pharmacy technicians or pharmacy interns authorized by the pharmacist on duty may remain in the pharmacy while the pharmacist is on lunch break;
- (7) During such times that the pharmacist is temporarily absent from the pharmacy, only pharmacy technicians or pharmacy interns duly authorized by the pharmacist on duty may continue to perform non-discretionary duties as delineated by the pharmacist. However, all duties performed by the technicians or interns shall be reviewed by the pharmacist upon his or her return from break;
- (8) When a pharmacist is not in the pharmacy, there shall be no dispensing or sale of new prescriptions that the pharmacist has checked and are waiting to be picked up nor shall counseling be provided by the pharmacy technician or pharmacy intern;
- (9) New, written prescriptions, presented in person by the patient or his agent, may be accepted by the pharmacy technician or pharmacy intern and the processing of that prescription, up to the final check, may occur during the absence of the pharmacist. However, no new prescriptions may be dispensed or sold until the final check is completed by the pharmacist on his or her return;
- (10) New prescriptions conveyed by telephone shall not be accepted and the caller shall be instructed to call back or a telephone number obtained for the pharmacist to call upon his or her return;
- (11) During the pharmacist's absence, prescription refills which have been previously prepared and checked by a pharmacist may be picked up by the patient or his agent. If the patient has no questions, the sale may proceed as normal with the patient signing a statement indicating the refusal of counseling by the pharmacist. If the patient desires counseling, he or she shall be asked to wait for the pharmacist to return from break or, alternatively, asked to leave a telephone number for the pharmacist to call later that day;
- (12) Telephone refill orders as well as refill requests presented, in person, by the patient or his agent, may be accepted by the pharmacy technician or intern and such refill orders may be processed by the technician or intern up to the final check. However, no such refill orders shall be dispensed or sold until the final check is completed by the pharmacist on his or her return from break;
- (13) A pharmacist who takes a lunch break in compliance with this protocol shall not be subject to New Hampshire state board of pharmacy disciplinary action or board citation for acts that he or she did not authorize and that he or she, by the exercise of reasonable care, could not have prevented during his or her absence; and

- (14) If in the professional judgment of the pharmacist, for reasons of security or otherwise, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy. All pharmacy technicians and pharmacy interns shall be removed from the pharmacy during his or her absence. A sign informing the public of the pharmacist's return shall be conspicuously posted.

Readopt with amendments 704.03, effective 3-26-05, (Doc. #8316), to read as follows:

Ph 704.03 Transmission of Prescription Drug Order by Prescriber.

- (a) A prescription drug order may be transmitted to a pharmacy by an authorized prescriber or his designated agent in writing, orally or electronically.
- (b) An electronically transmitted prescription drug or device order shall:
- (1) Be sent to the pharmacy of the patient's choice;
 - (2) For a non-controlled substance prescription drug or device order, include:
 - a. The name of the patient;
 - b. The name, strength, and quantity of the drug prescribed;
 - c. Any directions specified by the prescribing practitioner;
 - d. The name and address of the prescribing practitioner which shall be printed or typewritten;
 - e. The prescribing practitioner's phone number for verbal confirmation; and
 - f. The date the prescription was ordered.
 - (3) For a schedule III – IV controlled substance prescription drug order, as defined in RSA 318-B:1-b and transmitted by facsimile, include:
 - a. The name and address of the patient;
 - b. The name, strength, and quantity of the drug prescribed;
 - c. Any directions specified by the prescribing practitioner;
 - d. The full name of the prescribing practitioner which must be printed, rubber stamped, or typewritten above or below his or her handwritten signature;
 - e. The address of the prescribing practitioner;
 - f. The federal drug enforcement administration (DEA) number assigned to the prescribing practitioner; and
 - g. The date the prescription was ordered.
- (c) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the electronically transmitted prescription drug order which shall be consistent with existing federal or state laws and rules.

(d) For controlled substances in schedules III, IV or V, as defined in RSA 318-B:1-b, an electronically generated copy of a written, signed prescription transmitted by facsimile directly by the prescribing practitioner, or the practitioner's agent, to the pharmacy, may be used as the original prescription.

(e) For controlled substances in schedule II, as defined in RSA 318-B:1-b, a pharmacy may receive an electronically transmitted, by facsimile, drug order directly from the prescriber for filling, provided however, that the original written prescription, prepared in accordance with RSA 318-B:9, III and IV, shall be presented and verified against the electronic record at the time the substances are actually dispensed and that the original document shall be processed and retained for filing.

(f) There shall be 3 exceptions to the requirements stated in (e) above:

(1) A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, to be compounded for the direct administration to a patient in a private residence, long-term care facility, or hospice setting, by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be electronically transmitted, by facsimile, by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The facsimile shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I;

(2) A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, for a resident of a long-term care facility may be electronically transmitted by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The facsimile shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I; and

(3) A prescription prepared in accordance with RSA 318-B:9, III and IV, and issued for a schedule II substance, as defined in RSA 318-B:1-b, for a patient enrolled in a hospice care program, may be electronically transmitted, by facsimile, by the practitioner or the practitioner's designated agent to the dispensing pharmacy. The practitioner or the practitioner's designated agent shall note on the prescription that the patient is a hospice patient. The facsimile shall serve as the original written prescription and shall be maintained in accordance with the provisions of RSA 318-B:9, I.

(g) The device used for the receipt of electronically transmitted prescription drug orders shall be located in the prescription department of the pharmacy in order to protect patient confidentiality and to assure security.

Amend Ph 704.04 intro. and (a) – (d) effective 3-26-05, (Doc. #8316), to read as follows:

Ph 704.04 Transfer of Prescriptions. Original prescription drug order information for drugs may be transferred between pharmacies for the purpose of refill dispensing subject to the following:

- (a) The transfer shall be communicated directly between 2 licensed pharmacists;
- (b) The transferring pharmacist shall:
 - (1) Write the word "VOID" on the face of the prescription for controlled substances;
 - (2) Note in the patient medication record that a copy has been issued, the date of transfer, and the name of the pharmacist transferring the prescription; and
 - (3) Record in the patient medication record the name and address of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information.
- (c) When a prescription is transferred, no further refills shall be issued by the transferring pharmacy; and
- (d) The pharmacist receiving the transferred prescription information shall:
 - (1) Write the word "transfer" on the face of the transferred prescription; and
 - (2) Provide all information required to be on the prescription including the:
 - a. Patient's name and address;
 - b. Doctor's name and address;
 - c. Date of issuance of the original prescription and date of transfer;
 - d. Number of valid refills remaining and date of last refill;
 - e. Pharmacy name, address, and original prescription number from which the prescription information was transferred;
 - f. Full name of the transferor pharmacist; and
 - g. DEA registration number of the transferor pharmacy for controlled substances.

Amend Ph 704.06, paragraphs (b), (c), and (f), effective 3-26-05, (Doc. #8316), to read as follows:

- (b) Therapeutically equivalent drugs shall include only those drug products listed in "Approved Prescription Drug Products with Therapeutic Equivalence Evaluations"

published by the United States Department of Health and Human Services, according to RSA 146-B:2, I, or any written notification or confirmation from the federal Food and Drug Administration (FDA) that a drug product is a therapeutically equivalent drug product.

(c) The pharmacist shall not select an equivalent drug product:

- (1) If the prescriber handwrites “medically necessary” on the written prescription;
- (2) If when ordering a prescription orally, the prescriber specifies that the prescribed drug is medically necessary; or
- (3) If the prescription is electronically transmitted, the prescriber includes a statement on the face of the prescription indicating medically necessary.

(f) Unless the prescriber instructs otherwise, the label for every drug product dispensed shall include the product's trade or brand name, if any, or its established generic name and the name of the manufacturer, packer or distributor, using abbreviations such as the National Drug Code (NDC) number if necessary. In the interest of public health and safety, the pharmacist may, when dispensing a generic drug, include the brand name on the prescription label following the generic name. The brand name, however, shall be preceded or followed with the word "sub", indicating substituted for, or "I.C.", indicating interchanged for or “generic for”.

Readopt with amendments Ph 707.01, effective 3-26-05, (Doc. #8316), to read as follows:

Ph 707.01 Controlled Drug Destruction. Any person authorized to possess controlled drugs and desiring to dispose of such drugs may request destruction of the drugs by the board or request an authorization from the board to destroy such drugs.

Amend Ph 707.02(a), effective 3-26-05, (Doc. #8316), to read as follows:

(a) A request to destroy controlled drugs shall be in writing and signed by a duly authorized person as defined in (b) below. The itemized written request shall be conveyed to the board office and the destruction process shall not proceed until the authorization is received by the person who made the request.

Amend Ph 707.02(b)(1), effective 2-5-96, (Doc. #6181-B), as amended effective 2-1-99 (Doc. #6933), to read as follows:

- (1) Pharmacist-in-charge, as defined in RSA 318:1, X, practitioners or their designated agents;

Amend Ph 707.02(b)(7) and (c), effective 3-26-05, (Doc. #8316), to read as follows:

(b)(7) Director, New Hampshire division of public health services or his/her designated agent(s).

(c) The written request shall not be required when a consultant pharmacist, acting as an agent of the pharmacy board, destroys controlled drugs in a licensed long-term care or specialized care facility.

Amend 707.03 (b), effective 2-5-96, (Doc. #6181-B), as amended effective 2-1-99 (Doc. #6933), to read as follows:

(b) The pharmacist-in-charge at a licensed hospital pharmacy shall be responsible for overseeing the destruction of controlled substances, in accordance with the procedures as set by the hospital's Hazardous Waste Disposal Committee and at no expense to the state of New Hampshire. The destruction of controlled substances shall be performed by a registered pharmacist, employed by the institution, and witnessed by a second licensed healthcare professional or registered technician as designated by the pharmacist-in-charge. The pharmacist-in-charge shall:

(1) Create a record of such controlled drugs destroyed made on federal form DEA 41 obtained from the board office, identified in Ph 103.03; and

(2) Distribute copies of form DEA 41 as follows:

- a. The original shall be sent to the board office; and
- b. A copy shall be retained in the hospital pharmacy where the destruction occurred for a period of 4 years.

Amend 707.03 (c) and (d), effective 3-26-05, (Doc. #8316), by inserting new paragraph (c) and renumbering and amending existing paragraphs (c) and (d), to read as follows:

(c) In a patient care area of the institution, partially used, patient-specific controlled substances may be destroyed by one licensed healthcare professional and witnessed by a designee of the pharmacist-in-charge as described in the written policies and procedures of the institution relative to the accountability and method of destruction of such drugs.

(d) In the interest of the health and safety of group home residents, the facility's consultant pharmacist(s) may remove from such group homes any discontinued, expired or otherwise unusable drugs.

(e) In order to remove the drugs referenced in (d) above, the consultant pharmacist shall:

- (1) Notify the board that a request has been made by the facility,

to the consultant pharmacist, for removal of drugs;

(2) Submit to the board a written request for removal of such drugs;

(3) File one copy of form Ph 516, issued by the board pursuant to (2) above, at the group home; and

(4) Retain one copy with the drugs, which shall be removed to the consultant's place of practice.

(f) Upon receipt of the original of form Ph 516, a compliance investigator shall proceed to the consultant's place of practice to supervise the destruction of the drug.

Readopt with amendments Ph 709.01, effective 3-26-05, (Doc. #8316), to read as follows:

Ph 709.01 Definitions.

(a) “Automated medication supply system” means an electronically controlled system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(b) “Electronic signature”, for purposes of paragraph (a) above, means a unique security code or other identifier which specifically identifies the person entering information into a data processing system. An institution which utilizes electronic signatures shall maintain a permanent list of the unique security codes and the persons to whom they have been assigned.

(c) “Satellite pharmacy” means a pharmacy in an institutional setting under the direction of a licensed pharmacist, that is remote from the centrally licensed pharmacy, but within the same facility/location and dependent upon the centrally licensed pharmacy for administrative control, staffing and drug procurement.

Amend Ph 709.02(g), effective 2-5-96, (Doc. #6181-B), as amended effective 2-1-99 (Doc. #6933), to read as follows:

(g) Each institution shall have a pharmacy and therapeutics committee or a comparable committee of its medical staff. This committee shall be composed of representatives of the medical staff and the pharmacist-in-charge, or a licensed staff pharmacist designated by the pharmacist-in-charge, and representatives of the administrative and nursing departments. The committee shall meet at least twice a year. The major functions of this committee shall be to establish the written policies and procedures governing the practice of pharmacy, use of drugs, drug specifications and drug distribution.

Amend Ph 709.04, effective 3-26-05, (Doc. #8316), by adding new paragraphs (c) and (h) and renumbering and amending the existing paragraphs (c), (d), (e), and (f) as (d), (e), (f), and (g), to read as follows:

(c) When using an automated medication supply system, the pharmacist-in-charge shall have the responsibility for assigning, discontinuing, or changing personnel access codes.

(d) A pharmacist or registered pharmacy technician under the direction of a pharmacist shall visit and create a written record, at least monthly, all areas or departments of the institution where drugs, biologicals, pharmaceutical chemicals or other pharmaceutical preparations are stored to ensure that they are properly labelled, have not reached their expiration date and show no signs of deterioration. Any substance not conforming to these standards shall be removed from stock.

(e) A written record of each monthly inspection specified in (d) above shall be maintained in the pharmacy and shall be available to the board upon request.

(f) The pharmacist shall ensure that the areas specified in (d) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(g) The pharmacist-in-charge shall develop a distribution system which shall prevent the illicit diversion of drugs. When applicable, the inventory of all schedule II controlled substances and other controlled drugs as required by local, state and federal law stored in any area or department of the facility except the pharmacy shall be checked and recorded by 2 persons at least every 24 hours or at each shift change when using a manual dispensing system when the department is open or every 7 days when using an automated dispensing system and accountability records shall be maintained in the department of the facility or the pharmacy.

(h) When an emergency drug kit other than regulated by Ph 705.03, containing controlled substances is opened, shift counts shall be done by the nursing staff on all controlled substances until resealed by a pharmacist.

Amend Ph 709.05(a), effective 3-26-05, (Doc. #8316), to read as follows:

(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, physician, dentist, optometrist, ~~or~~ advanced registered nurse practitioner, physician assistant or podiatrist in compliance with local, state and federal pharmacy-related laws and rules. Upon the written order of a physician, dentist, optometrist, advanced registered nurse practitioner, physician assistant or podiatrist, a nurse may leave a properly labelled container of any non-controlled drug at the patient's bedside. A licensed nurse shall not dispense or compound drugs except as permitted by RSA 318:42.

Amend Ph 709.05(c)(5), effective 3-26-05, (Doc. #8316), to read as follows:

- (5) Signature of the prescriber or licensed health care professional receiving the order.

Amend Ph 709.07(d), effective 2-5-96, (Doc. #6181-B), as amended effective 2-1-99 (Doc. #6933), to read as follows:

- (d) This record shall be separate from the patient's chart and include:

- (1) Name and address of the patient;
- (2) Name of the medical practitioner;
- (3) Name, strength and quantity of the drug(s);
- (4) Date of administration or dispensing; and
- (5) Signature or electronic designation, as defined in Ph 709.01(b), of the agent removing the drug(s) from the inventory.

Readopt with amendments 709.08, effective 3-26-05, (Doc. #8316), to read as follows:

Ph 709.08 Investigational Drugs. Investigational drugs for research shall be used only under the supervision of the principal investigator and shall be approved by an appropriate medical staff committee. Such drugs shall be controlled by the pharmacy and shall be properly labelled. A central unit, which may be the pharmacy, shall be established where essential information on investigational drugs is maintained. Nurses shall be given basic pharmacologic information about the drug before administering.

Amend Ph 803.01, effective 7-25-01 (Doc. #7535), by adding new paragraph (c), renumbering current paragraph (c) as (d), to read as follows:

- (c) An applicant for registration as a registered pharmacy technician shall meet the following requirements:

- (1) Be at least 18 years of age or have a high school or equivalent diploma, or be working to achieve a high school or equivalent diploma;
- (2) Be of good moral character;
- (3) Shall not have been convicted of a drug-related felony or admitted to sufficient facts to warrant such findings; and

(4) Shall have training or experience as determined by the pharmacist-in-charge.

(d) Applicants for registration shall submit an application form PT-1 for registration to the board that contains the following:

- (1) Name, residence address, home telephone number and social security number of the applicant;
- (2) Date and place of birth of the applicant;
- (3) Name of current employer and address of employment site;
- (4) Record of convictions of violations of federal, state or local drug or pharmacy related laws or regulations;
- (5) Any felony convictions;
- (6) Applicant's signature and date; and
- (7) The prescribed fee which shall be \$25.

Amend Ph 807.01, effective 7-25-01 (Doc. #7535), by amending paragraphs (a), (b), (c), and (e) to read as follows:

(a) It shall be the responsibility of the pharmacist-in-charge to identify pharmacy technicians and to assure that such persons are registered with the board as pharmacy technicians within 30 days of employment.

(b) All pharmacy technicians shall wear a name tag, identifying them as a “Pharmacy Technician”, while on duty.

(c) The pharmacist on duty shall determine the duties of the pharmacy technician based upon the needs of the pharmacy. Pharmacy technicians shall be limited to performing tasks in the preparation of legend drugs and devices and to provide nonjudgmental technical support services, as defined in Ph 807.01.

(e) The pharmacist shall verify and confirm the correctness, exactness, accuracy and completeness of the acts, tasks, and functions undertaken by the pharmacy technician who assists the pharmacist in the practice of pharmacy.